

October 2007



# Minnesota Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

University Park Plaza  
2829 University Ave SE, Suite 530  
Minneapolis, MN 55414-3251  
[www.phcybrd.state.mn.us](http://www.phcybrd.state.mn.us)

## Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of June 16, 2007 and September 12, 2007.

**Boris, Angie. License #116034.** Ms Boris admitted to theft of controlled substances (CS) from her employer and the unauthorized personal use of those drugs. Her license was suspended for an indefinite period of time, and she was assessed a \$500 civil penalty.

**Bullerman, Miles. License #111765.** Mr Bullerman admitted to the theft of CS from his employer and the unauthorized personal use of those drugs. His license was placed on probation until he successfully completes the Health Professionals Services Program (HPSP) and meets all requirements imposed by the substance abuse court, whichever is later. He was also assessed a \$200 civil penalty.

The Board took the following disciplinary actions concerning **technicians** between the dates of June 16, 2007 and September 12, 2007.

The following pharmacy technicians had their registrations suspended: **Brown, Alisha, Registration #716070; Jachymowski, Leanne, Registration #705550; Johnson, Betty Lou, Registration #702202; Melin, Judi, Registration #704835; Nicholls, Kerry, Registration #711487.**

## Adoption of Rules Package

On May 14, 2007, a notice of "Adopted Permanent Rules Relating to Pharmacy Regulations" was published in the *Minnesota State Register*. This was the final step in the adoption of a package of rule changes that the Board had worked on for over two years. The rule changes officially went into effect on May 21, 2007. Several documents relating to the rule changes are available on the Board's Web site, including an unofficial version of the changed rules.

The Board began highlighting information about specific rule changes in the last edition of this *Newsletter*. Information about rule changes concerning nonsterile and sterile compounding follows.

## Nonsterile Compounding

The Board replaced several rules concerning the equipment and record-keeping requirements for nonsterile compounding with a requirement that all "licensed Minnesota pharmacies that compound nonsterile drug preparations must follow United States Pharmacopeia (USP), Chapter 795, standards." USP Chapter 795 contains standards for facilities and equipment, stability and beyond-use dating, ingredient selection, the compounding process, record keeping and documentation, and quality control. Thirteen steps are given that, if followed, help to minimize error and maximize the benefit of the product for the patient.

A complete discussion of USP Chapter 795 is beyond the scope of this *Newsletter*. USP Chapter 795 is available in the *Pharmacists' Pharmacopeia*, a publication of the USP that is a comprehensive reference for a number of areas of pharmacy practice.

## Sterile Compounding

The Board now also requires that any "licensed Minnesota pharmacy compounding a sterile product must follow the United States Pharmacopeia, Chapter 797, standards." USP Chapter 797 sets standards that apply to all settings in which sterile preparations are compounded and to all professionals who are engaged in such compounding. USP Chapter 797 is also available in the *Pharmacists' Pharmacopeia*. First adopted as an enforceable standard in 2004, USP Chapter 797 is in the process of being revised. Information concerning the proposed revisions of the chapter can be obtained on the USP Web site at [www.usp.org/USPNF/pf/generalChapter797.html](http://www.usp.org/USPNF/pf/generalChapter797.html).

## Provider Cost Disclosure

During the 2006 session, health licensing boards were directed to remind licensees, at least annually, of the price disclosure requirements of Minnesota Statutes (MS) §62J.052 or §151.214, as applicable. Pharmacists must abide by MS §151.214, which states:

Subdivision 1. **Explanation of pharmacy benefits.** A pharmacist licensed under this chapter must provide to a patient, for each prescription dispensed where part or all of

*Continued on page 4*



## Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at [www.fda.gov/cder/meeting/medication\\_guides\\_200706.htm](http://www.fda.gov/cder/meeting/medication_guides_200706.htm).

## Reporting Makes a Difference



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**<sup>®</sup> Community/Ambulatory Edition by visiting [www.ismp.org](http://www.ismp.org). If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://www.ismp.org)) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System*, and *Identifying and Preventing Medication Errors*, the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- ◆ Losec<sup>®</sup> (error reports indicating mistaken as Lasix<sup>®</sup>) to Prilosec<sup>®</sup>,
- ◆ Levoxine (error reports indicating mistaken as Lanoxin<sup>®</sup>) to Levoxyl<sup>®</sup>,
- ◆ Reminyl<sup>®</sup> (error reports indicating mistaken as Amaryl<sup>®</sup>) to Razadyne<sup>™</sup> (and unfortunately new error reports show Razadyne being mistaken as Rozerem<sup>™</sup>)



- ◆ and the most recent, Omacor® (error reports indicating mistaken as Amicar®) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit [www.ismp.org](http://www.ismp.org) and click on "Report Errors."

## **FDA Finds Consumers Still Buying Potentially Risky Medications via Internet**

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "inherently unsafe practice." FDA also encourages consumers to review [www.fda.gov](http://www.fda.gov) for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

- ◆ inadequate labeling for safe use;
- ◆ inappropriate packaging and, therefore, uncertain product integrity;
- ◆ possible previous withdrawal from the US market for safety or efficacy reasons;
- ◆ drug-specific risks requiring initial screening and/or periodic patient monitoring;
- ◆ potential harm or abuse, such as with the use of controlled substances; and
- ◆ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

## **Death in Canada Tied to Counterfeit Drugs Bought via Internet**

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

## **FDA Sets Standards for Dietary Supplements**

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at [www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments).

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at [www.cfsan.fda.gov/~dms/dscgmps7.html](http://www.cfsan.fda.gov/~dms/dscgmps7.html) and a fact sheet at [www.cfsan.fda.gov/~dms/dscgmps6.html](http://www.cfsan.fda.gov/~dms/dscgmps6.html).

More information is available on the FDA Unapproved Drugs Web site at [www.fda.gov/cder/drug/unapproved\\_drugs/default.htm](http://www.fda.gov/cder/drug/unapproved_drugs/default.htm).

the cost of the prescription is being paid or reimbursed by an employer-sponsored plan or health plan company, or its contracted pharmacy benefit manager, the patient's co-payment amount and the pharmacy's own usual and customary price of the prescription or the amount the pharmacy will be paid for the prescription drug by the patient's employer-sponsored plan or health plan company, or its contracted pharmacy benefit manager.

Subd. 2. **No prohibition on disclosure.** No contracting agreement between an employer-sponsored health plan or health plan company, or its contracted pharmacy benefit manager, and a resident or nonresident pharmacy registered under this chapter, may prohibit the pharmacy from disclosing to patients information a pharmacy is required or given the option to provide under subdivision 1.

## **Continuing Education**

### **Certificate of Completion**

Although we are only midway through the two-year continuing education (CE) cycle, some pharmacists have already completed their required 30 hours of CE. During each cycle, pharmacists must submit a Certification of Completion of Continuing Education form. In the past, the form has been mailed to pharmacists. It is now available for download from the Board's Web site at [www.phcybrd.state.mn.us/forms/cecercert08.pdf](http://www.phcybrd.state.mn.us/forms/cecercert08.pdf).

### **Continuing Education for Preceptors**

In order to renew registration as a preceptor, a pharmacist must have participated in an instructional program specifically for preceptors, provided or approved by the Board, within the previous 24 months. At its September 18, 2007 meeting, the Board designated additional CE programs as being acceptable for this purpose. Please refer to the "Interns and Preceptors" portion of the Board's Web site for additional information. There are now three online CE programs approved for the preceptor CE requirement:

- ◆ "Pharmacy Law: The Pharmacist's Role in a Quality System to Prevent Medication Errors." Ken Baker, RPh, JD. Accreditation Council for Pharmacy Education (ACPE) #372-000-04-013-H03.
- ◆ "Prescription Errors: Legal Consequences and Patient Safeguards." David B. Brushwood, RPh, JD. Powerpak. ACPE #430-000-05-104-H03.
- ◆ "The Community Pharmacist Preceptor Education Program." Developed by the American Pharmacists Association and National Association of Chain Drug Stores. ACPE #206-202-07-008-H04.

All three programs are available online, are ACPE approved, and are free. Links to the program are available on the Board's Web site: [www.phcybrd.state.mn.us/preceptorce.htm](http://www.phcybrd.state.mn.us/preceptorce.htm). In addition to the online CE programs, the University of Minnesota College of Pharmacy periodically holds CE programs for preceptors.

## **Changing Information on Schedule II Prescriptions**

Board staff members are often asked about what information can be changed (or added) to a Schedule II prescription by a pharmacist. The following answer, which is posted on the Board's Web site, is from the United States Drug Enforcement Administration.

The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consultation with the prescribing practitioner, the pharmacist is permitted to change the patient's address, drug strength, drug quantity and directions for use. The pharmacist is permitted to make information additions that may be provided by the patient or bearer such as the patient's address, and such additions should be verified. The pharmacist may also add the dosage form to the prescription order after verification with the prescribing practitioner.

The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature. These types of changes challenge the necessity of the original prescription and would require a new prescription from the prescribing practitioner.

## **Changes of Address**

Board staff will soon be mailing out renewal notices for technicians. Renewal notices for pharmacists will be mailed out in late December. You can change your mailing address using the online licensee services feature of the Board's Web site. You may also notify the Board of address changes via mail or by calling the Board offices. Notifying the Board of an address change is required by rule, and it minimizes the chance that a licensee or registrant will not receive a renewal notice. Every year, a number of individuals end up paying late fees because they have failed to notify the Board of an address change, never receive their renewal notices and, consequently, do not renew on time.